**UNPUBLISHED**

**UNITED STATES COURT OF APPEALS**

**FOR THE FOURTH CIRCUIT**

IGEN INTERNATIONAL, INCORPORATED,
a Delaware Corporation,
Plaintiff-Appellee,

v.

ROCHE DIAGNOSTICS GMBH,

No. 99-1465

Defendant-Appellant,

and

BOEHRINGER MANNHEIM GMBH, a
German Limited Liability Company,
Defendant.

Appeal from the United States District Court
for the District of Maryland, at Greenbelt.
Peter J. Messite, District Judge.
(CA-97-3461-PJM)

Argued: October 27, 1999

Decided: December 30, 1999

Before WILKINSON, Chief Judge, and WILKINS and
MICHAEL, Circuit Judges.

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Affirmed by unpublished per curiam opinion.

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**COUNSEL**

**ARGUED:** John Robert Dawson, Milwaukee, Wisconsin, for Appellant. Howard M. Shapiro, WILMER, CUTLER & PICKERING,

Washington, D.C., for Appellee. **ON BRIEF:** Michael A. Bowen, Michael J. Aprahamian, Milwaukee, Wisconsin; Joseph D. Edmondson, Jr., FOLEY & LARDNER, Washington, D.C., for Appellant. Stephen H. Sachs, Denise Esposito, Amy T. Kreiger, Heather A. Wydra, WILMER, CUTLER & PICKERING, Washington, D.C., for Appellee.

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Unpublished opinions are not binding precedent in this circuit. See Local Rule 36(c).

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**OPINION**

PER CURIAM:

Roche Diagnostics GmbH (Roche) appeals an order of the district court granting a preliminary injunction to IGEN International, Inc. (IGEN) in IGEN's suit alleging that Roche was violating a licensing agreement. Roche also appeals the denial of its motion to alter or amend the injunction. Finding no error, we affirm.

I.

IGEN is a biotechnology firm that is incorporated in Delaware with its principal place of business in Gaithersburg, Maryland. IGEN develops and markets technologies for use in medical diagnosis, including a diagnostic process based on electrochemiluminescence ("ECL"). In 1992, IGEN entered into a licensing agreement regarding the ECL technology with Roche. Pursuant to the agreement, Roche was to develop, manufacture, and market applications of the ECL ("instruments") and the tests and supplies used with the instruments. The agreement limited Roche to marketing its instruments within a "field" defined in the agreement. The agreement defined the field as

> the use of any Instrument to perform Assays, solely for use in hospitals (except where the performance of the Assay takes place at the side of the patient), blood banks and clini-

> cal reference laboratories. "Field" does not include, among other things, use of any Instrument or Assay in the presence or the proximity of the patient, e.g., for home, patient bedside, ambulance or physician office uses.

J.A. 616. The agreement also contained a provision explicitly reserving rights in all non-field applications of the ECL technology to IGEN:

> [Roche] agrees and acknowledges that IGEN retains for itself and its licensees the rights to any and all fields of use other than the Field and to any and all instruments other than those falling within the definition of Instruments herein, including, without limitation, the exclusive right to develop ... and sell or license an instrument for use in intensive care, emergency room, and other hospital patient bedside settings where the assay is performed at the patient's side, as well as home and physician office applications.

Id. at 622.

Pursuant to the agreement, Roche developed and, in 1996, began marketing two instruments using the ECL technology, the Elecsys 1010 and the Elecsys 2010. Each instrument weighs between 150 and 250 pounds and is intended for use in a laboratory, rather than at the side of the patient. Roche has marketed both instruments to non-hospital laboratories, including laboratories located within the office of a physician or group of physicians.

Since 1992, IGEN has been attempting to develop an instrument based on the ECL technology for application in the point-of-care diagnostic market. IGEN envisions a miniaturized instrument employing the ECL technology (an "ECLM") that can be used at the side of a patient and that will provide accurate results within 15 minutes, allowing physicians to make immediate decisions about patient care. Although IGEN thus far has been unsuccessful in developing such an instrument, it has been attempting to engage a corporate partner to invest in the development of the ECLM.

In the summer or fall of 1997, a Roche representative visited the office of Dr. Daniel Cohen, a shareholder of IGEN, for the purpose of selling Dr. Cohen and his partner an Elecsys instrument for use in their in-office laboratory. In October, Dr. Cohen mentioned the potential sale to IGEN's chief financial officer, who asked Dr. Cohen to learn more about Roche's sales of the Elecsys to other doctors' offices. In March 1998, Dr. Cohen sent IGEN a letter summarizing his findings that five practices had purchased an Elecsys instrument for use in their in-office laboratories.

Shortly thereafter, IGEN moved in the district court for a preliminary injunction preventing Roche from making further sales of Elecsys instruments to physicians' offices for use in in-house laboratories. IGEN asserted that Roche was marketing the Elecsys instruments to physicians' offices in violation of the licensing agreement and that Roche's marketing activities were deterring potential partners from investing in IGEN's attempts to develop the ECLM. After nearly three months of discovery, Roche filed an opposition to the motion for preliminary injunction claiming, inter alia , that injunctive relief was improper because IGEN had failed to comply with dispute resolution procedures outlined in the licensing agreement.

The district court granted the preliminary injunction after considering evidence obtained during discovery and hearing arguments from the parties. First, the court rejected Roche's argument that IGEN should be required to pursue contractual dispute resolution procedures, reasoning that Roche waived the argument by failing to raise it before discovery was conducted. With respect to IGEN's request for preliminary injunctive relief, the court concluded that IGEN had demonstrated that the denial of a preliminary injunction would cause it irreparable harm in that IGEN was losing a potential market for the ECLM and was having difficulty attracting corporate partners to invest in the ECLM technology. The court further found that Roche faced only a loss of sales during the course of the litigation. Based on these determinations, the court ruled that the balance of hardships favored IGEN. The court also concluded that IGEN had shown a substantial likelihood of success on the merits, reasoning that the plain language of the agreement indicated that the field in which Roche could market its instruments did not include any physician's office,

irrespective of whether the instrument would be used in an in-office laboratory or at a patient's side.

The district court directed the parties to negotiate the specific terms of the injunction, which they did over the course of the next several months. IGEN and Roche were unable to agree to all of the details of the injunction and accordingly submitted proposals to the district court, which then drafted an order. As relevant to this appeal, the injunction prohibits Roche from marketing Elecsys instruments and "any products and accessories that can be used only with the Elecsys system" to "physicians' offices or physicians' office laboratories." Id. at 572. The injunction defines "physicians' office laboratories" as:

> (a) laboratories that are located within the office suites of physicians' practices and
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> (b) laboratories that are located outside of physicians' offices but that are operated by or under the control of one or more treating physicians.
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> This definition of physicians' office laboratories expressly includes all laboratories that are operated by or under the control of physicians with practices of all types and sizes, including large group practices and conglomerations of such group practices, no matter where located. This definition excludes physician-controlled or operated laboratories that have no relationship with and are not operated as part of the practice or practices of the controlling or operating physicians. That is, physician ownership or operation in and of itself does not define a "physicians' office laboratory"; rather, to be considered a physicians' office laboratory (1) the owning, operating, or controlling physicians must send a significant portion of their patient samples to that laboratory or (2) the laboratory must conduct a significant portion of its overall testing on samples from patients of the owning, operating, or controlling physicians.

Id. Shortly thereafter, Roche moved to alter or amend the judgment, arguing that the definition of "physicians' office laboratories" did not account for the manner in which diagnostic laboratories are operated

in Germany, and thus might preclude Roche from marketing its product to those laboratories even though they were clinical reference laboratories as contemplated in the licensing agreement. The district court denied the motion to alter or amend.

II.

When ruling on a request for a preliminary injunction, a district court must consider four factors originally set forth in Blackwelder Furniture Co. v. Seilig Manufacturing Co., 550 F.2d 189 (4th Cir. 1977). Those factors are:

> (1) the likelihood of irreparable harm to the plaintiff if the preliminary injunction is denied,
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> (2) the likelihood of harm to the defendant if the requested relief is granted,
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> (3) the likelihood that the plaintiff will succeed on the merits, and
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> (4) the public interest.

Rum Creek Coal Sales, Inc. v. Caperton, 926 F.2d 353, 359 (4th Cir. 1991) (internal quotation marks omitted). After deciding whether the plaintiff will suffer irreparable harm if an injunction is denied and determining the nature of the harm, if any, that defendant will suffer if the injunction is granted, the district court must balance these hardships against one another. See Direx Israel, Ltd. v. Breakthrough Med. Corp., 952 F.2d 802, 812-13 (4th Cir. 1991). The result of this balancing determines the degree to which the plaintiff must establish a likelihood of success on the merits. If the balance of harms "tips decidedly in favor of the plaintiff," it is only necessary for the plaintiff to "raise[] questions going to the merits so serious, substantial, difficult and doubtful, as to make them fair ground for litigation and thus for more deliberate investigation." Id. at 813 (internal quotation marks omitted). If, however, the balance of harms is in equipoise or does not favor the plaintiff, the plaintiff must make a correspondingly higher showing of the likelihood of success. See id. We review a deci-

sion of the district court granting or denying preliminary injunctive relief for abuse of discretion, and we review underlying factual findings for clear error. See Rum Creek Coal Sales , 926 F.2d at 358. We review the grant or denial of a motion to alter or amend for abuse of discretion. See Pacific Ins. Co. v. American Nat'l Fire Ins. Co., 148 F.3d 396, 402 (4th Cir. 1998), cert. denied, 119 S. Ct. 869 (1999).

Having reviewed the record and the parties' briefs, and having had the benefit of oral argument, we conclude that the district court correctly decided the issues before it. Accordingly, we affirm.

AFFIRMED